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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/021,970	12/13/2001	Marcus B. Gohlke	068349.0120	4120

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 05/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/021,970

Applicant(s)

GOHLKE, MARCUS B.

Examiner

Susan D. Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5-18 and 25-39 is/are pending in the application.
- 4a) Of the above claim(s) 25-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3 and 5-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 19, 2005 has been entered.

2. Applicant has added claims 19-33. These number are incorrect. The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not). This application was filed with 24 claims. Claims 19-24 were cancelled by applicant in the amendment filed August 7, 2002.

Misnumbered claims 19-33 have been renumbered 25-39. It is requested that applicant amend the claims to correct the errors in dependency generated by the renumbering.

3. Method claims 25-39 are drawn to an invention that is considered independent and distinct from the previously examined composition claims, claims 1, 3, and 5-18 (see Restriction Requirement, part of the Office action mailed February 8, 2002). Applicant has indicated that they wish the method claims to be examined rather than the previously examined composition claims. However, this is improper. As discussed in MPEP section 706.07(h):

Applicants cannot file an RCE to obtain continued examination on the basis of claims that are independent and distinct from the claims previously claimed and examined as a matter of right (i.e., applicant cannot switch inventions). See 37 CFR 1.145. Any newly

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submitted claims that are directed to an invention that is independent and distinct from the invention previously claimed will be withdrawn from consideration...

4. Accordingly, claims 25-39 are withdrawn from consideration as being drawn to an invention that is independent and distinct from the previously claimed and examined invention.

5. Claims 1, 3, and 5-18 are examined on the merits. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

6. Claims 1, 3, and 5-15 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 97/08960 for the reasons set forth in the previous Office action.

The English translation of WO '960 is US Pat. No. 6,306,453. US '453 will be referred to for convenience.

Applicant's arguments submitted November 4, 2004 have been considered. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not anticipate the stated claims because the reference does not teach that the composition can be administered "safely" for two weeks. However, applicant's claims are drawn to composition claims, not to a method of administering a composition. The prior art composition contains the same ingredients claimed by applicant. Thus, since the compositions are the same, the reference composition must have the same characteristics in regards to safety or applicant's invention does not function as claimed.

7. Claims 1, 5, 6, 8, 9, and 12-15 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat. No. 6,241,983 for the reasons set forth in the previous Office action.

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Applicant's arguments submitted November 4, 2004 have been considered. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not anticipate the claimed invention because the reference composition requires ingredients that are not claimed in applicant's composition. However, applicant's claims use the broad transitional phrase "comprising." As discussed in MPEP section 2111.03, "The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps...". Thus, the reference properly anticipates the stated claims because applicant's claims encompass unrecited elements.

In addition, applicant argues that the reference does not anticipate the stated claims because the reference does not teach that the composition can be administered "safely" for two weeks. However, applicant's claims are drawn to composition claims, not to a method of administering a composition. The prior art composition contains the same ingredients claimed by applicant. Thus, since the compositions are the same, the reference composition must have the same characteristics in regards to safety or applicant's invention does not function as claimed.

8. Claims 1, 3, and 5-17 are rejected under 35 U.S.C. 102(e) as being anticipated by US 2002/0119928 for the reasons set forth in the previous Office action.

Applicant's arguments submitted November 4, 2004 have been considered. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not anticipate the claimed invention because the reference composition requires ingredients that are not claimed in applicant's

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composition. However, applicant's claims use the broad transitional phrase "comprising." As discussed in MPEP section 2111.03, "The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps...". Thus, the reference properly anticipates the stated claims because applicant's claims encompass unrecited elements.

In addition, applicant argues that the reference does not anticipate the stated claims because the reference does not teach that the composition can be administered "safely" for two weeks. However, applicant's claims are drawn to composition claims, not to a method of administering a composition. The prior art composition contains the same ingredients claimed by applicant. Thus, since the compositions are the same, the reference composition must have the same characteristics in regards to safety or applicant's invention does not function as claimed.

Claim Rejections - 35 USC § 103

9. Claims 1, 7, 10, 11, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 97/08960 for the reasons set forth in the previous Office action.

Applicant's arguments submitted November 4, 2004 have been considered. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the claimed invention is patentable over the reference because applicant has demonstrated unexpected benefits in the safe administration of the composition for at least two weeks. Applicant points out the declaration filed May 7, 2004 as support for this claim of unexpected results. The declaration discusses the toxic effects seen when beta glucan

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and lactoferrin are taken separately for an extended period of time. The declaration asserts that these effects are not present when the two are administered together. However, as discussed above, the reference teaches a composition that is the same as the composition claimed by applicant. The only difference between the claimed invention and the reference composition is the amounts of each ingredient that are present in the composition. Thus, applicant's allegations of unexpected results must hinge on this difference. Applicant has not demonstrated that the specific amounts of the composition claimed produce an unexpected difference. Thus, the stated claims are still considered obvious based on the reference.

10. Claims 1, 3, 7, 10, 11, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 6,241,983 in view of US Pat. No. 5,670,138 for the reasons set forth in the previous Office action.

Applicant's arguments submitted November 4, 2004 have been considered. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant reiterates the argument that the invention has unexpected results in regards to the length of administration. However, as discussed above, the primary reference, US '983, teaches a composition that is the same as applicant's claimed composition. Thus, the unexpected results must stem from limitations that are not anticipated. Applicant has not demonstrated that the unanticipated, i.e. rejected as obvious, limitations produce any unexpected benefit. Thus, the claims are still considered obvious over these references.

In addition, applicant argues that there is no motivation to combine the two references together. However, US '983 teaches oral pharmaceutical products and US '138 teaches ingredients that are well known in the art to be appropriate ingredients for oral pharmaceutical

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products. Thus, a person of ordinary skill in the art would reasonably expect that these ingredients can be used to create an oral product. Therefore, an artisan of ordinary skill in the art would be motivated to use lemon flavoring, mannitol, sorbitol, and silicon dioxide in combination with the beta-glucan and lactoferrin to formulate an orally administered product.

11. Claims 1, 3, 7, 10, 11, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 2002/0119928 in view of US Pat. No. 5,670,138 for the reasons set forth in the previous Office action.

Applicant's arguments submitted November 4, 2004 have been considered. All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant reiterates the argument that the invention has unexpected results in regards to the length of administration. However, as discussed above, the primary reference, US '928, teaches a composition that is the same as applicant's claimed composition. Thus, the unexpected results must stem from limitations that are not anticipated. Applicant has not demonstrated that the unanticipated, i.e. rejected as obvious, limitations produce any unexpected benefit. Thus, the claims are still considered obvious over these references.

In addition, applicant argues that there is no motivation to combine the two references together. However, US '928 teaches oral pharmaceutical products and US '138 teaches ingredients that are well known in the art to be appropriate ingredients for oral pharmaceutical products. Thus, a person of ordinary skill in the art would reasonably expect that these ingredients can be used to create an oral product. Therefore, an artisan of ordinary skill in the art would be motivated to use lemon flavoring, mannitol, sorbitol, and silicon dioxide in combination with the beta-glucan and lactoferrin to formulate an orally administered product.

12. No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.

Susan D. Coe

S-12-05

Susan D. Coe
Primary Examiner
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